UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	)	**FILED UNDER SEAL**
v.	)	**No. 10-cr-694-RWT**
LAUREN STEVENS,	)	
Defendant.	)	

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT'S CORRECTED MOTION IN LIMINE TO EXCLUDE EVIDENCE
OUTSIDE THE SCOPE OF THE ALLEGATIONS OF THE INDICTMENT

The Indictment in this case charges Ms. Stevens, a former Vice President and Associate General Counsel of GlaxoSmithKline ("GSK"), with obstruction of justice and false statements based on GSK's response to a Food and Drug Administration ("FDA") inquiry regarding possible off-label promotion of GSK's antidepressant medication Wellbutrin SR.[1] The Indictment alleges Ms. Stevens made false and misleading statements about GSK's promotion of Wellbutrin in a series of response letters to the FDA, and thereby obstructed the FDA's inquiry. All of the Indictment's allegations relate to alleged off-label promotion of Wellbutrin.

In response to inquiries from the defense, the Government has indicated it intends to introduce evidence that Ms. Stevens' counsel believes goes beyond the facts alleged in the Indictment. The Government has provided some information regarding the types of evidence at issue, but has declined to provide a complete statement of what this additional evidence may cover. (Ms. Stevens' motion for a bill of particulars remains pending.)

Ms. Stevens, through counsel, now respectfully moves this Court *in limine* to limit the Government's evidence to that which is relevant to the allegations contained in the Indictment, and specifically to exclude any evidence relating to: (1) any alleged off-label promotion of any

[1] The Indictment refers to GSK as "K-Corp.," and to Wellbutrin as "W-Drug."

drug other than Wellbutrin ; (2) any alleged off-label promotion that occurred outside the time period covered by the FDA's investigation and the Defendant's response letters (January 1, 2001 through October 9, 2002, *see* Ind. ¶ 14); and (3) any alleged off-label promotion that the government cannot proffer to have been known by Ms. Stevens during the time of her response letters to the FDA (October 9, 2002 through November 26, 2003, *see* Ind. ¶¶ 25-41).

Any evidence that relates to off-label promotion of drugs other than Wellbutrin, off-label promotion outside the period covered by the FDA's investigation and Ms. Stevens' letters, or conduct that was not known by Ms. Stevens at the time of her charged statements to the FDA is irrelevant under Federal Rule of Evidence 401 and should be excluded under Federal Rule of Evidence 402. This evidence is not probative of any of the offense conduct charged in the Indictment. Its admission would neither advance nor rebut the core issues to be tried: whether, in the letters charged in the Indictment, Ms. Stevens wrongfully made false statements or concealed evidence in response to the FDA's inquiry into the promotion of Wellbutrin.

Moreover, Federal Rule of Evidence 403 bars this evidence. Its admission would confuse and mislead the jury, and work unfair prejudice, by inviting the jury to consider against Ms. Stevens conduct not charged in the indictment, including conduct by others that Ms. Stevens neither knew of nor participated in. Such admission would conflate alleged wrongdoing by GSK with the actions charged against Ms. Stevens, and invite the jury to impute guilt to Ms. Stevens for uncharged conduct by others rather than for her own actions charged in the Indictment.

BACKGROUND

This trial is one very thin slice of a very large Government investigation. The Indictment raises a discrete set of allegations against a single individual, regarding a discrete series of representations about GSK's promotion of a single drug (Wellbutrin) over a short and defined time period (January 1, 2001 to October 9, 2002). Through this motion in limine, the Defendant seeks

to keep the evidence at trial focused on the specific charges leveled against her in the Indictment, and to prevent the Government from enlarging the scope of this trial by bringing in, without advance notice, unspecified evidence from its much larger investigation concerning other individuals, other drugs, and other time periods.

The Government is using a grand jury in Boston to conduct a wide-ranging investigation into alleged off-label promotion of prescription drugs by Ms. Stevens' employer, the pharmaceutical manufacturer GSK. The grand jury investigation began in late 2003 or early 2004, and continues today. Based on materials produced in discovery, the investigation appears to be a sweeping investigation of the company as a whole, involving many different drugs, many different individuals, and a broad time period. Neither the company nor any individuals other than Ms. Stevens have been charged; the investigation is ongoing.

As detailed in the Indictment, this case concerns a year-long inquiry by the FDA, from Fall 2002 to Fall 2003, into alleged off-label promotion of a single drug, Wellbutrin SR, and a discrete series of response letters Ms. Stevens sent to the FDA between February and November 2003 in response to that inquiry. On October 9, 2002, GSK received a letter (the "Request") from the FDA requesting information about GSK's promotional activities relating to unapproved or "off label" uses of Wellbutrin SR. Ind. ¶ 3.[2] Ms. Stevens, an Associate General Counsel at GSK, led a legal team of GSK attorneys, paralegals, and outside counsel that drafted GSK's voluntary response to the FDA's Request. Through several teleconferences and written correspondence between October 11 and October 29, 2002, the parties agreed that the Request's focus was limited to off-label promotion of Wellbutrin between January 1, 2001 and October 9, 2002. *See, e.g.,* Ind. ¶ 14.[3] Ms. Stevens sent to the FDA six substantive letters in which she

[2] The FDA's October 9, 2002 Request letter is attached as Ex. 1.

[3] Ms. Stevens' letters to the FDA confirm that they relate to the January 1, 2001 to October 9, 2002 timeframe. *See* Letter dated Oct. 29, 2002, at 2 (Ex. 2); Letter dated Feb. 28, 2003, at 1 (Ex. 3); Letter dated Mar. 28, 2003, at 1 (Ex. 4); Letter dated May 21, 2003, at 1 (Ex. 5).

submitted on a rolling basis materials within these parameters.

The six-count Indictment concerns the content of four of these letters. Count One charges obstruction of an official proceeding (18 U.S.C. § 1512), and alleges that Ms. Stevens obstructed the FDA inquiry by making false and misleading statements to the FDA and by concealing from the FDA documents and other information about GSK's promotion of Wellbutrin. Ind. at 11. Count Two charges falsification of records (18 U.S.C. § 1519), and alleges that Ms. Stevens sent false letters, falsified and altered documents, and concealed and covered up GSK's promotional activities of Wellbutrin, with intent to impede the FDA's inquiry. Ind. at 12. Counts Three through Six charge false statements (18 U.S.C. § 1001), and allege that in four identified letters, Ms. Stevens knowingly and willfully made false statements regarding GSK's promotion of Wellbutrin. Ind. at 13, 15, 16, 18.

Every allegation in the Indictment concerns GSK's promotion of Wellbutrin. *See* Ind. ¶¶ 2-4, 11, 12-41; Ind. at 11 (Count One), 12 (Count Two), 13-14 (Count Three), 15 (Count Four), 16-17 (Count Five), 18 (Count Six). No other drug is mentioned in the Indictment.

PROCEDURAL POSTURE

On November 8, 2010, the grand jury in this District handed up the Indictment against Ms. Stevens. Ms. Stevens has filed eight pre-trial Motions which are currently pending, including a Motion for a Bill of Particulars (Dkt. 23), which seeks specification of the conduct the Government intends to prove to support the two obstruction counts (Counts One and Two). Though the Government has declined to provide the requested particulars for these two counts, it has indicated, in conversations with counsel, that it intends to offer at trial proof of purported misconduct by GSK employees other than Ms. Stevens that is not alleged in the Indictment.

In response to Rule 16 discovery requested by Ms. Stevens' counsel, the Government has made a rolling (and continuing) production of databases, copies of hard drives, and miscellane-

ous CD-ROMs of responsive materials. ***So far, this production exceeds fifteen million pages.*** So far, only a fraction of the produced materials appear to relate to the allegations in the Indictment regarding off-label promotion of Wellbutrin.[4]

Trial is on an accelerated schedule and set for April 5, 2011.

DISCUSSION

By this motion, the Defendant seeks to narrow the evidence the Government may introduce to that which is relevant to the allegations in the Indictment. The Indictment's allegations relate exclusively to GSK's alleged off-label promotion of Wellbutrin, and to an alleged cover-up of evidence regarding promotion of Wellbutrin. The time period the FDA was investigating, and the corresponding timeframe for which Ms. Stevens responded on behalf of GSK, was expressly limited to January 1, 2001 to October 9, 2002. *E.g.*, Ind. ¶ 14.

This Court should limit the evidence at trial to that which relates to GSK's off-label promotion of Wellbutrin during that period. Additionally, the Court should limit the evidence regarding alleged off-label promotion at GSK to evidence which the Government can proffer was known to Ms. Stevens during the time she was responding to the FDA inquiry (October 9, 2002 to November 6, 2003, *see* Ind. ¶¶ 3, 12-41). All other evidence should be excluded under Federal Rules of Evidence 402 and 403.

I. Under Rules 401 and 402, the Court should limit the evidence to that which is relevant to the allegations in the Indictment

"It is elementary that, for evidence to be admissible, it must be relevant to an issue being tried." *United States v. Hedgepeth*, 418 F.3d 411, 419 (4th Cir. 2005) (citing Fed. R. Evid. 402). "Relevant evidence is evidence that has 'any tendency to make the existence of any fact that is of

[4] The defense is not critical of the breadth of the Government's production. The defense made broad discovery requests to try to prepare to meet any evidence the Government may seek to put on. The fact that the parties have exchanged evidence in response to cautiously broad requests, however, does not mean such evidence is relevant for trial.

consequence to the determination of the action more probable or less probable than it would be without the evidence.'" *Id.* (quoting Fed. R. Evid. 401). Relevancy must be determined "in relation to the charges and claims being tried," not to charges or defenses not at issue in the case. *Id.* (citing *United States v. Prince-Oyibo*, 320 F.3d 494, 501-02 (4th Cir. 2003)); *accord United States v. Lamberty*, 778 F.2d 59, 60 (1st Cir. 1985) (framework for determining relevancy "consists of elements of the offense[s] charged and any relevant defenses"). Evidence that does not relate to the elements of the charges being tried is irrelevant and should be excluded under FRE 402. *Hedgepeth*, 418 F.3d at 419-20.

A. All of the allegations in the Indictment relate to GSK's off-label promotion of Wellbutrin from January 1, 2001 to October 9, 2002

The only evidence which is relevant to the charges being tried is that which is probative of proving or rebutting the conduct charged in the Indictment. *See Hedgepeth*, 418 F.3d at 419; FRE 401. The allegations in the Indictment relate exclusively to GSK's promotion of Wellbutrin, and to Ms. Stevens' responses to the FDA concerning promotion of Wellbutrin. *See* Ind. ¶¶ 2-4, 11-41. Every count of the Indictment is predicated on GSK's promotion of Wellbutrin.[5]

The representations by Ms. Stevens which the Government contends are false or otherwise culpable are contained exclusively in a series of four letters from Ms. Stevens responding to the FDA's inquiry into promotion of Wellbutrin. In the section of the Indictment titled,

[5] *See* Ind. at 11 (Count One, obstruction) (concerning "promotional activities by K-Corp. for W-Drug"); Ind. at 12 (Count Two, falsification of records) (concerning "promotional activities including gifts and entertainment by K-Corp. for W-Drug"); Ind. at 13-14 (Count Three, false statements (reciting statements from Feb. 28, 2003 letter concerning promotion of W-Drug, and stating additional allegations regarding promotion of W-Drug); Ind. at 15 (Count Four, false statements) (reciting statement from March 28, 2003 letter, which concerned attendees at 2001-02 Speaker Events related to Wellbutrin, *see* Ex. 4 at 2); Ind. at 16-17 (Count Five, false statements) (reciting statements from May 21, 2003 letter relating to promotion of W-Drug, and stating additional allegations regarding promotion of W-Drug); Ind. at 18 (Count Six, false statement) (reciting statement about W-Drug and stating additional allegation regarding promotion of W-Drug).

"STEVENS' False Representations To and Concealing of Evidence from the FDA" (Ind. at 5) (which is incorporated in each Count), the Government contends that "STEVENS signed and sent to the FDA a series of letters . . . in which she made materially false statements and concealed and covered up documents and other evidence that showed the extent of K-Corp.'s promotion of W-Drug for unapproved uses." Ind. ¶ 25. Paragraphs 26 through 41 of the Indictment describe four of those letters and the allegedly false statements in them concerning GSK's promotion of Wellbutrin. The Indictment does not allege that Ms. Stevens made false, misleading, or otherwise culpable statements to the FDA outside the four letters described in paragraphs 25 through 41 of the Indictment.

The FDA's Request was expressly limited both in subject matter and timeframe. As to subject matter, the Request was prompted by the FDA's concerns that GSK was promoting Wellbutrin for off-label purposes. Ind. ¶ 3; Ex. 1.[6] The Request's fifteen enumerated points repeatedly and explicitly sought information pertaining only to GSK's off-label promotion of Wellbutrin. Ex. 1 at 1-3. As to time frame, GSK and the FDA specifically agreed that "the time period covered by the FDA's request for information and materials was from January 1, 2001, to October 9, 2002." Ind. ¶ 14; *see* Ex. 2 at 2. Each of the false statement counts (Counts Three through Six) is expressly predicated on "statements regarding [GSK]'s activities from January 1,

[6] Paragraph 3 of the Indictment states: "On or about October 9, 2002, the [FDA] sent a letter to K-Corp. [GSK] that stated that the FDA had become aware of information that [GSK] had possibly promoted the use of W-Drug [Wellbutrin] for an unapproved use—specifically for weight loss. The FDA asked [GSK] about its W[ellbutrin] promotional programs and asked [GSK] to provide materials related to W[ellbutrin] promotional programs, including copies of all slides, videos, handouts, and other materials presented or distributed at any [GSK] program or activity related to W[ellbutrin]. In the letter, the FDA also asked [GSK] to identify any compensation provided to individuals involved in programs or activities related to W[ellbutrin]."

The FDA's Request letter (Ex. 1) specifically states the inquiry concerns "the possible promotion of Wellbutrin SR . . . in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations," that is, that GSK "may be promoting the off-label use of Wellbutrin SR for weight loss." Ex. 1 at 1. The Request makes no mention of any other drug.

2001, through October 9, 2002." Ind. at 13, 15, 16, 18. The letters underlying Counts Three through Five (incorporated by reference in Counts One, Two, and Six, *see* Ind. at 11, 12, 18) each expressly state that "the information provided herein and responsive to your requests covers the period January 1, 2001 through October 9, 2002." Ex. 3 at 1, Ex. 4 at 1, and Ex. 5 at 1.

The Indictment is thus plainly and exclusively focused on GSK's promotion of Wellbutrin from January 1, 2001 to October 9, 2002; the truthfulness of Ms. Stevens' representations regarding the results of GSK's investigation into the same; and whether, by her charged statements to the FDA, Ms. Stevens corruptly sought to obstruct or impede the FDA's inquiry into promotion of Wellbutrin during that time period. The only evidence that makes these facts more or less probable, FRE 401; *Hedgepeth*, 418 F.3d at 419, is evidence concerning GSK's promotion of Wellbutrin during this period, and evidence concerning what Ms. Stevens learned in her investigation into GSK's promotion of Wellbutrin over the same period. Any other evidence should be excluded as irrelevant under FRE 402.

B. Evidence of GSK's alleged off-label promotion of other drugs and off-label promotion outside of the investigative period is irrelevant

The law of the Fourth Circuit is clear: evidence that neither advances nor counters an element of the charges is irrelevant. *See Hedgepeth*, 418 F.3d at 420; *United States v. Prince-Oyibo*, 320 F.3d 494, 501-02 (4th Cir. 2003). Accordingly, the Court should exclude as irrelevant any evidence relating to alleged off-label promotion of drugs other than Wellbutrin, or to alleged off-label promotion outside the period covered by GSK's responses to the FDA inquiry.

Hedgepeth is instructive. There, a Richmond city councilwoman was tried on charges that she had solicited and accepted a bribe in exchange for her support for a mayoral candidate. 418 F.3d at 414-16. The cooperating bribe-payer was permitted to testify, over objection, that he approached the councilwoman because he thought "Gwen Hedgepeth might be in the kickback business." *Id.* at 417. The Government offered two reasons for admitting the statement: first, to

show the cooperator's reason for approaching the defendant, and second, to show the cooperator's "conspiratorial mindset," to support the conspiracy charge. *Id.* at 419.

The Fourth Circuit found the statement irrelevant, and its admission error under both Rule 401 and Rule 403. First, with regard to the cooperator's motive for approaching Hedgepeth, assertedly offered to rebut any suggestion the prosecution had targeted Hedgepeth, the court ruled this was "hardly probative of any 'fact that is of consequence to the determination of the action,'" *id.* at 419-20 (quoting Rule 401), and that "[t]he FBI's motive in investigating Hedgepeth has not been shown to be probative of any element of the offenses being tried." *Id.* at 420. The briber's alleged motive was not relevant to any element of the bribery or extortion charges, and because no entrapment defense was asserted, it also was not admissible to rebut such a defense. *Id.* The admission of the statement was thus error under Rule 401.[7]

The Court of Appeals further rejected the government's assertion that the briber's statement of his own motive was relevant to establishing a conspiratorial agreement. *See id.* Because the cooperator had already pled guilty to conspiring to bribe the councilwoman, the Fourth Circuit concluded the probative value of the cooperator's statement that he thought Hedgepeth "might be in the kickback business" was "marginal, at best." *Id.* Even to the extent the statement had any marginal probative value, the court concluded such value was outweighed by the statement's substantial and unfair prejudicial impact under Rule 403. *Id.*

Similarly, in *Prince-Oyibo*, a visa fraud case, the Fourth Circuit upheld the exclusion of the defendant's proffered evidence that he was a Christian subject to religious discrimination by Nigeria's Muslim majority. *Id.* at 497, 501. The defendant offered this evidence to explain why he would not have questioned the large sum of money he had paid to obtain the visa (which was fraudulent). *Id.* at 501. The Fourth Circuit ruled that the only issues for the jury were whether

[7] After ruling that admission of the statement was error, the appellate court found the error harmless on the facts of the case. *Id.* at 421.

the visa was counterfeit and whether the defendant knew it, and evidence of religious discrimination was not relevant to proving or disproving his knowledge that the visa was false. *Id.* at 501-02; *see also id.* at 497. Because the evidence was not relevant to the elements in dispute, it was properly excluded. *Id.* at 502.

As in *Hedgepeth* and *Prince-Oyibo*, this Court should exclude as irrelevant any evidence that does not relate to the elements of the offenses charged, to wit, the truth or falsity of Ms. Stevens' statements regarding GSK's promotion of Wellbutrin during the relevant time period, and Ms. Stevens' state of mind regarding the FDA's inquiry into promotion of Wellbutrin. Any evidence relating to alleged off-label promotion of other drugs, or alleged off-label promotion outside the time period covered by the FDA's inquiry and Ms. Stevens' statements, is not relevant to prove or disprove the allegations in the Indictment, and should be excluded.

C. Evidence regarding promotion of Wellbutrin should be limited to that which the Government proffers was known to Ms. Stevens when she responded to the FDA

Evidence of GSK's off-label promotion of Wellbutrin during the period covered by the FDA's inquiry is also irrelevant unless Ms. Stevens knew of it at the time she responded to the FDA. Any evidence of off-label drug promotion that was not known by Ms. Stevens when she responded cannot be probative of whether she knowingly, willfully, or corruptly misled the FDA, or did so with intent to impede the FDA's inquiry.

Each of the Indictment's charges requires proof of a specific criminal scienter. For Count One, obstruction of an official proceeding under § 1512 requires proof that Ms. Stevens acted "corruptly." Ind. at 11; *see* § 1512(c)(2). For Count Two, falsification of records under § 1519 requires that Ms. Stevens "knowingly" falsified or concealed evidence with the specific intent to "impede, obstruct, or influence" the FDA's investigation. Ind. at 12; *see* § 1519. For Counts Three through Six, the false statements statute, § 1001, requires proof that Ms. Stevens "know-

ingly and willfully" made false statements in response to the Request. Ind. at 13, 15, 16, 18; *see* § 1001(a).

Evidence of third-party conduct can only be relevant to Ms. Stevens' state of mind under these statutes if she had knowledge of the activity. Any evidence of third-party conduct, including asserted off-label promotion of GSK products, cannot be relevant to Ms. Stevens' state of mind unless Ms. Stevens knew of such third-party conduct.

The required link between third-party conduct and the defendant's state of mind was squarely addressed in *United States v. St. Michael's Credit Union*, 880 F.2d 579 (1st Cir. 1989). There, a credit union was convicted of currency transaction reporting violations, and its treasurer was convicted of knowingly and willfully aiding and abetting the credit union's unlawful conduct. *Id.* at 581-83. At trial, the court allowed the government to introduce evidence that the treasurer's father had been running an illegal gambling operation at the credit union, in order to try to show willfulness on the treasurer's part—*i.e.*, that she had failed to report currency transactions in order to hide her father's gambling activities. *Id.* at 599-600. On appeal, the employee argued that any evidence regarding her father's gambling was irrelevant absent proof that she had known about those alleged activities. *Id.* at 599. The First Circuit agreed. *Id.* at 601.

The First Circuit found no proof that the employee knew of her father's alleged activities, and no evidence from which the jury could have inferred that she must have known. *Id.* at 600-01. Absent proof of knowledge, the appellate court ruled "the gambling evidence was irrelevant," and that its admission was "an abuse of discretion on relevancy grounds" under Rules 401 and 402. *Id.* at 601. Other courts have agreed that absent proof that the defendant knew about it, evidence of third-party misconduct is irrelevant. *See United States v. Snook*, 366 F.3d 439, 443 (7th Cir. 2004) (upholding exclusion of evidence of third-party conduct offered by the defendant to negate intent, "absent some evidence [the defendant] knew about it," because "unless there's

some link-up to [the] defendant, all we're dealing with is . . . various inferences upon inferences of speculation"); *United States v. Rosen*, 520 F. Supp. 2d 802, 813 (E.D. Va. 2007) (stating that third-party conduct that occurred outside the presence of the defendant is only relevant to the defendant's state of mind if the defendant became aware of it).

As in *St. Michael's*, the Court should exclude any evidence of third-party conduct that the government cannot link to Ms. Stevens. Like the employee in *St. Michael's*, Ms. Stevens is charged in her individual capacity. *Unlike* the employee in *St. Michael's*, Ms. Stevens is not charged alongside her employer, nor is she charged with aiding and abetting her employer. Rather, she charged *only* for her own individual actions. As such, the only evidence bearing on her culpability is evidence of actions of which she had knowledge. Any evidence of alleged off-label promotion by others at GSK (whether of Wellbutrin or other drugs, at any time inside or outside the FDA's inquiry period) is not probative of Ms. Stevens' state of mind unless she knew about it. Admitting any evidence of third-party conduct without proof of Ms. Stevens' knowledge would impermissibly allow the jury to impute misconduct to Ms. Stevens based upon pure speculation and conjecture. FRE 401 and 402 are designed specifically to prevent this risk.

In light of the Government's refusal to particularize its allegations, we cannot know what evidence of third-party conduct, if any, the Government intends to introduce. And, obviously, disputed issues regarding whether Ms. Stevens knew of various actions at GSK cannot be resolved preliminarily on a motion *in limine*. But in light of the vast body of evidence the Government has produced regarding its entire company-wide investigation at GSK, it is well possible, indeed apparently likely, that the Government intends to introduce evidence of activity at GSK well beyond what is alleged in the Indictment and well beyond Ms. Stevens' own actions or responsibilities. In that case, the Government should be required at the outset at least to proffer how it intends to connect any such evidence to Ms. Stevens. If the Government is not able to

proffer that Ms. Stevens knew of alleged unlawful conduct at GSK by others, the Government should be precluded from offering such third-party conduct into evidence against Ms. Stevens.

In addition, to be relevant to the charges in the Indictment, any evidence of off-label promotion at GSK must have been known to Ms. Stevens at the time of the charged offense conduct. Ms. Stevens is charged with having made false or misleading responses to the FDA between the time she learned of the FDA's inquiry (October 9, 2002) and the date of her last response letter to the FDA (November 6, 2003).[8] To the extent that the Government intends to offer any evidence of *off-label promotion* at GSK after November 6, 2003, not only is such evidence not relevant to the time period covered by the FDA's inquiry and GSK's response letters (January 1, 2001 to October 9, 2002), but such information could not have affected Ms. Stevens' knowledge at the time she made her representations to the FDA between October 9, 2002 and November 6, 2003. Thus, the Court should exclude any evidence of post-November 2003 off-label promotion unless the Government can prove how such evidence can show Ms. Stevens' state of mind between October 2002 and November 2003.

II. Evidence regarding off-label promotion of other drugs or during other time periods, or regarding conduct outside Ms. Stevens' knowledge, should also be excluded under Rule 403

Even if relevant, evidence should be excluded under Rule 403 if "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403; *Hedgepeth*, 418 F.3d at 420. In criminal cases, evidence is unfairly prejudicial if it "lure[s] the fact finder into declaring guilt on a ground different from proof specific to the offense charged." *Old Chief v. United States*, 519 U.S. 172, 180 (1997).

[8] Counts One and Two of the Indictment charge that Ms. Stevens' obstruction and falsification continued "through at least in or about January 2004," Ind. at 11, 12, but the Indictment contains no allegation of any conduct by Ms. Stevens after November 6, 2003, *see* Ind. ¶¶ 38-41.

A. Evidence regarding off-label promotion of other drugs or during other times periods, or regarding conduct outside Ms. Stevens' knowledge, would work unfair prejudice and confuse and mislead the jury by inviting conviction based on conduct other than that charged

Even if evidence about promotion of other drugs or activities beyond Ms. Stevens' knowledge were somehow relevant to the Indictment's allegations about her statements about Wellbutrin, such evidence should be excluded under Rule 403 because its admission would work unfair prejudice and confuse and mislead the jury as to the issues charged in the Indictment.

First, evidence regarding alleged off-label promotion of other drugs or during time periods other than that investigated by the FDA would invite the jury to "declar[e] guilt on a ground different from proof specific to the offense charged." *Old Chief*, 19 U.S. 172 at 180. As argued above, the charges in the Indictment relate exclusively to off-label promotion of Wellbutrin, and to alleged false representations by Ms. Stevens about the promotion of Wellbutrin during the period under investigation, January 1, 2001 to October 9, 2002. If the Government is permitted to introduce evidence regarding promotion of other drugs, or promotion of Wellbutrin outside the period covered by the FDA's inquiry and GSK's responses, the jury will be invited to consider guilt based on conduct other than that charged in the Indictment. In addition, evidence of off-label promotion of other drugs by GSK would invite the jury to conflate conduct by *GSK*, which is not on trial, with the charged conduct against *Ms. Stevens*, who is charged as an individual, and charged only with misrepresentations and concealment regarding Wellbutrin. The jury would be invited to impute alleged wrongdoing by *GSK* to Ms. Stevens, and to form an opinion of guilt by association. Such evidence thus poses a substantial risk of unfairly prejudicing Ms. Stevens, and confusing and misleading the jury. *See, e.g.*, *Hedgepeth*, 418 F.3d at 420-21 (citing *United States v. Grossman*, 400 F.3d 212, 218-19 (4th Cir. 2005); *see also United States v. Koger*, 646 F.2d 1194, 1197-98 (7th Cir. 1981) (excluding under Rule 403 evidence that "was not shown to have anything to do with the charges against the [defendant]" and invited the jury

to speculate as to how the evidence showed the defendant's guilt); *United States v. LaRouche*, 896 F.2d 815, 826-27 (4th Cir. 1990) (affirming the exclusion of evidence that "would divert the jury from the issues raised in the indictment," where the probative value was "substantially outweighed by the distraction it would cause").

Second, absent proof that Ms. Stevens knew of GSK's alleged off-label promotion at the time she made the charged responses to the FDA, this evidence would invite the jury to convict without satisfaction of the individual *mens rea* required for conviction. As the First Circuit explained in *St. Michael's Credit Union*, evidence of third-party misconduct should be excluded as unduly prejudicial under FRE 403 unless there is proof that connects the third party's conduct to the defendant's criminal scienter. 880 F.2d at 602. This nexus precludes the jury from implicitly and impermissibly linking the misconduct of third parties to an innocent defendant. *Id.* Such concerns are acute in this case. Instead of focusing on the truth or falsity of Ms. Stevens' letters to the FDA and her state of mind at the time she submitted those letters, the jury would be invited to consider GSK's alleged wrongdoing, independent of the Indictment's charges against Ms. Stevens, and potentially to convict Ms. Stevens based on guilt by association. Again, GSK is not on trial; only Ms. Stevens is. Rule 403 supports exclusion of evidence from which the jury might impute vicarious liability to Ms. Stevens for GSK's alleged wrongdoing, rather than focusing on the specific conduct charged against Ms. Stevens as an individual.

B. Evidence about other drugs or other conduct by GSK would also needlessly extend the trial, wasting the time of the Court, the jury, and the parties

There is a third reason to exclude evidence regarding off-label promotion of other drugs, or other alleged misconduct at GSK: the need to prevent a time-consuming and confusing sideshow before the jury, and the concomitant need to permit Ms. Stevens and her counsel, as they prepare for this imminent trial, to focus their efforts on the issues charged in the Indictment,

rather than preparing to defend against other uncharged conduct.

This trial is set to begin in approximately six weeks. It is projected to last four weeks. That time before the jury, and the parties' time to prepare, will be well filled by trial of the issues charged in the Indictment relating to promotion of Wellbutrin. Permitting the trial of uncharged allegations regarding other drugs and other uncharged conduct at GSK is too much, and would risk spending a great deal of trial time on a sideshow that bears no relation to Ms. Stevens' guilt or innocence of the offenses charged by the grand jury.

To date, the government has produced over ten gigabytes of information, some fifteen million pages, of which only a fraction is material to the allegations and charges in the Indictment. The introduction of such evidence, which spans promotion of other drugs, other individuals with no relationship with Ms. Stevens, and unproven allegations of impropriety involving issues other than off-label promotion, would exponentially increase amount of information before the jury but provide no corresponding clarity to the charges facing Ms. Stevens. This evidence would waste the time of both the Court and jury on issues that are, at best, tangentially related to Ms. Stevens' guilt. The sheer volume of the discovery in this case would guarantee that both the government's case-in-chief and the required rebuttal evidence would likely extend the length of trial well beyond the current schedule.

Just as significantly, permitting the introduction of evidence of conduct beyond that charged in the Indictment would require a huge diversion of the defense's energy and resources in preparing for trial. In the six weeks between now and trial, the defense has a substantial task ahead in preparing to try the facts and issues charged in the Indictment. Allowing trial of uncharged issues as well will require defense counsel to waste valuable resources trying to anticipate what other issues the Government will put on—and to sift through literally millions of pages of discovery to try to find what the Government intends to prove. Though this problem is often

addressed in the bill of particulars context,[9] it is equally appropriate, especially where trial is accelerated as here, to prevent unfair prejudice by narrowing the issues for trial to those that are charged in the Indictment. After all, "[t]he law does not expect a man to be prepared to defend every act of his life which may be suddenly and without notice alleged against him." *United States v. Burr*, 25 F. Cas. 55, 159, 170 (C.C.D. Va. 1807) (Marshall, C.J.). Limiting the trial evidence to the conduct charged in the Indictment would prevent such prejudice and permit defense counsel to prepare fairly and effectively for trial.

CONCLUSION

For the foregoing reasons, the Could should limit testimony and evidence at trial to GSK's alleged off-label promotion of Wellbutrin during the period covered by the FDA's inquiry and GSK's responses (January 1, 2001 to October 9, 2002), and should exclude evidence of (1) any alleged off-label promotion of any drug other than Wellbutrin; (2) any alleged off-label promotion that occurred outside the time period covered by the FDA's investigation and the Defendant's response letters (January 1, 2001 through October 9, 2002); and (3) any alleged off-label promotion that the government cannot proffer to have been known by Ms. Stevens during the time of her response letters to the FDA (October 9, 2002 through November 26, 2003).

[9] *See, e.g.*, *United States v. Savin*, No. 00 CR 45 (RWS), 2001 WL 243533, at *3 (S.D.N.Y. Mar. 7, 2001) (requiring bill of particulars where defendant would be "forced to comb though this veritable mountain of documents and to attempt to guess which of the numerous transactions documented therein . . . are alleged by the government to have been improper"); *see also United States v. Bortnovsky*, 820 F.2d 572, 574-75 (2d Cir. 1987) (holding that the "Government did not fulfill its obligation merely by providing mountains of documents to defense counsel who were left unguided as to which documents would be proven falsified"); *United States v. Nachamie*, 91 F. Supp. 2d 565, 571 (S.D.N.Y. 2000) (bill of particulars necessary where Government produced more than 200,000 documents relating to 2,000 Medicare claims without identifying which claims it contended were fraudulent).

Respectfully submitted,

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By: /s/

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